UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P.O. Box 1450 Alexandria, Virginia 22313-1450 www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/087,449	02/28/2002	Michael L. Blomquist	14485.0141US01	9068
23552 MERCHANT &	7590 08/03/200 & GOULD PC	EXAMINER		
P.O. BOX 2903	}		NORTON, JENNIFER L	
MINNEAPOLIS, MN 55402-0903			ART UNIT	PAPER NUMBER
			2121	
			MAIL DATE	DELIVERY MODE
			08/03/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

	Application No.	Applicant(s)				
Office Action Occurrence	10/087,449	BLOMQUIST, MICHAEL L.				
Office Action Summary	Examiner	Art Unit				
	Jennifer L. Norton	2121				
The MAILING DATE of this communication app Period for Reply	ears on the cover sheet with the c	orrespondence address				
A SHORTENED STATUTORY PERIOD FOR REPLY WHICHEVER IS LONGER, FROM THE MAILING DATE - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication. If NO period for reply is specified above, the maximum statutory period was a Failure to reply within the set or extended period for reply will, by statute, Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).	ATE OF THIS COMMUNICATION 36(a). In no event, however, may a reply be time will apply and will expire SIX (6) MONTHS from cause the application to become ABANDONE	lely filed the mailing date of this communication. (35 U.S.C. § 133).				
Status						
1)⊠ Responsive to communication(s) filed on <u>06 Ju</u>	dv 2009.					
	action is non-final.					
<i>;</i> —	Since this application is in condition for allowance except for formal matters, prosecution as to the merits is					
	closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.					
Disposition of Claims						
4)⊠ Claim(s) <u>1-25</u> is/are pending in the application.						
4a) Of the above claim(s) is/are withdrawn from consideration.						
5) Claim(s) is/are allowed.						
6)⊠ Claim(s) <u>1-25</u> is/are rejected.						
7) Claim(s) is/are objected to.						
8) Claim(s) are subject to restriction and/or	election requirement.					
Application Papers						
9) The specification is objected to by the Examiner.						
10)⊠ The drawing(s) filed on <u>28 February 2002</u> is/are: a)⊠ accepted or b)□ objected to by the Examiner.						
Applicant may not request that any objection to the	·- · ·- ·	•				
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).						
11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.						
Priority under 35 U.S.C. § 119						
12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of:						
1. Certified copies of the priority documents	1. Certified copies of the priority documents have been received.					
2. Certified copies of the priority documents						
3. Copies of the certified copies of the priority documents have been received in this National Stage						
application from the International Bureau (PCT Rule 17.2(a)).						
* See the attached detailed Office action for a list of the certified copies not received.						
Attachment(s)						
1) Notice of References Cited (PTO-892) 4) Interview Summary (PTO-413)						
2) Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Da 5) Notice of Informal P					
3) Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date 5) Notice of Informal Patent Application 6) Other:						

Art Unit: 2121

DETAILED ACTION

1. The following is a **Non-Final Office Action** in response to the Request for Continued Examination filed on 06 July 2009. Claims 1, 12 and 19 have been amended. Claims 1-25 are pending in this application.

Response to Arguments

- 2. Applicant's arguments see Remarks pgs. 8-9, filed 06 July 2009 with respect to rejection of claims 12-25 under 35 U.S.C. 102(e) have been considered but are moot in view of the new ground(s) of rejection.
- 3. Applicant's arguments see Remarks pgs. 9-12, filed 06 July 2009 with respect to the rejection of claims 1-25 under 35 U.S.C. 103(a) have been considered but are moot in view of the new ground(s) of rejection.
- 4. Claims 1-25 stand rejected under 35 U.S.C. 103(a) as set forth below.

Claims

5. <u>Examiner Notes:</u> a) The Examiner notes Applicant's use of the clause "configured to/for" in claims 3 and 11; and "wherein" in claims 2-8 and 10, 11, 14-17 and 21-25. The Applicant is reminded that use of "configured to/for" and "wherein" does not exclude the definition/interpretation of optional components and/or steps, i.e.

Art Unit: 2121

the apparatus, system or method may or may not have the components and/or steps, per MPEP 2111.04, recited below for convenience:

2111.04 [R-3] "Adapted to," "Adapted for," "Wherein," and "Whereby" Clauses

Claim scope is not limited by claim language that suggests or makes optional but does not require steps to be performed, or by claim language that does not limit a claim to a particular structure. However, examples of claim language, although not exhaustive, that may raise a question as to the limiting effect of the language in a claim are:

- (A) "adapted to "or "adapted for "clauses;
- (B) "wherein "clauses; and
- (C) "whereby "clauses.

The determination of whether each of these clauses is a limitation in a claim depends on the specific facts of the case. In Hoffer v. Microsoft Corp., 405 F.3d 1326, 1329, 74 USPQ2d 1481, 1483 (Fed. Cir. 2005), the court held that when a "whereby' clause states a condition that is material to patentability, it cannot be ignored in order to change the substance of the invention." Id. However, the court noted (quoting Minton v. Nat 'l Ass 'n of Securities Dealers, Inc., 336 F.3d 1373, 1381, 67 USPQ2d 1614, 1620 (Fed. Cir. 2003)) that a "whereby clause in a method claim is not given weight when it simply expresses the intended result of a process step positively recited.""

Claim Objections

6. Applicant's arguments, see Remarks pg. 8, filed 06 July 2009 with respect to the objection of claims 1 and 12 have been fully considered and are persuasive. The objections of claims 1 and 12 have been withdrawn.

Art Unit: 2121

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

- (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 8. Claims 1, 8, 12 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Publication No. 2003/0114836 A1 (hereinafter Estes) in view of U.S. Patent No. 5,814,015 (hereinafter Gargano).
- 9. As per claim 1, Estes teaches a method of programming an ambulatory infusion pump (Fig. 1, element 100) from a computer (pgs. 3-4, par. [0034] and [0035] and Fig. 2, element 132), the ambulatory infusion pump programmed to execute a delivery program (pgs. 3-4, par. [0034]), the delivery program being driven by operating parameters (pg. 3, par. [0032] and [0033]), the method comprising:

generating a table (Fig. 3A, element 300) on an interface displayed by the computer the computer having a computer peripheral (col. 6, par. [0054]), the table (Fig. 3A) containing a row, the row having a plurality of cells (pg. 6, par. [0054]; i.e. corresponding operating parameters and cells, e.g. Max Bolus: 5.7U, Time Display: 24 Hr., Beep Volume: 3), and each cell in the row relating to a different operating parameter for the delivery program (pg. 6, par. [0054]; i.e. corresponding operating parameters and cells, e.g. Max Bolus: 5.7U, Time Display: 24 Hr., Beep Volume: 3); and

downloading the operating parameters into the pump (pgs. 3-4, par. [0035], Fig. 1 and 2, elements 106 and 132 and Fig. 3A, element 300).

Estes teaches a user interface displayed (Fig. 3B-3D) by the computer the computer having a computer peripheral (pgs. 2-3, par. [0027] and pg. 6, par. [0056]) but does not expressly teach generating a table on a user-interface displayed by the computer having a computer peripheral, entering an operating parameter into at least one of the cells in the table, the operating parameter being entered directly into the at least one of the cells through the computer peripheral.

Gargano teaches to a graphical user interface (Fig. 17, element 204 and 206) displayed by a control unit (Fig. 1, element 12) having a peripheral (col. 4, lines 24-46 and col. 6, lines 35-39 and Fig. 1, element 24, 30 and 32; i.e. knobs for user input and a display), entering an operating parameter (col. 11, lines 40-49; i.e. entering operating parameters via Fig. 17, element 204 and 206 (Setup screens)), the operating parameter being entered directly through the peripheral (col. 4, lines 24-46; i.e. entering operating parameters using Fig. 1, element 24, 30, and 32).

Therefore, it would have been obvious to a person of ordinary skill in the art at the time of applicant's invention to modify the teaching of Estes to include a graphical user interface displayed by a control unit having a peripheral, entering an operating parameter, the operating parameter being entered directly through the peripheral to

Art Unit: 2121

provide a method of customization entry of drug information for a wide range of drug types and chemistries (col. 1, lines 28-34).

10. As per claim 8, Estes teaches a method of operating a pump (Fig. 1, element 100), the pump having a memory (pgs. 3-4, par. [0035] and Fig. 1, element 106) and a pump mechanism (pg. 3, par. [0029]), the method comprising:

receiving from a computer, a plurality of data sets, each data set in the plurality of data sets containing a plurality of operating parameters (Fig. 3A, element 300; Fig. 2, elements 100 and 132; pgs. 3-4, par. [0035]; Fig. 5, Alarm/Event Marker Table; pg. 6, par. [0060], i.e., "The graph is derived from carbohydrate consumption events from the event marker table that have been logged by the user"; pg. 7, [0063], i.e., "the time change is displayed in either 12 or 24 hr format depending on user's settings"; pg. 7, par. [0064], i.e., "At least some of these events can be taken as inputs to the bolus estimator 128 in calculating an insulin dosage"),

storing the plurality of data sets in memory (pgs. 3-4, par. [0035] and Fig. 1, element 106);

selecting one of the plurality of data sets (pg. 8, par. [0008]) and Fig. 6, i.e. SUSPEND, BOLUS, BASAL); and

running a delivery program wherein the delivery program executes the operating parameters in the selected one of the plurality of data sets, the operating parameters

defining a delivery schedule for controlling the pump mechanism (pg. 8, par. [0073] and Fig. 6, BOLUS DELIVERY).

Estes does not expressly teach wherein each data set in the plurality of data sets contains the same type of operating parameters and at least two of the data sets contain different values for the same type of operating parameter.

Gargano teaches wherein data sets contain the same type of operating parameters (col. 11, lines 40-49; e.g. syringe manufacturer and size; infusion units or type; mode or drug name; concentration; patient weight; infusion rate; bolus amount and duration; and dose amount, dose duration, number of doses and dose interval) and at least two of the data sets contain different values for the same type of operating parameter (col. 14, lines 33-36; i.e. entering new information of a new drug by user selection).

Therefore, it would have been obvious to a person of ordinary skill in the art at the time of applicant's invention to modify the teaching of Estes to include wherein data sets contain the same type of operating parameters and at least two of the data sets contain different values for the same type of operating parameter to provide a method of customization entry of drug information for a wide range of drug types and chemistries (col. 1, lines 28-34).

11. As per claim 12, Estes teaches a method of operating an infusion pump (Fig. 1, element 100) for delivering a therapeutic agent into the body of a user (pg. 3, par. [0029]), the infusion pump being programmable (pgs. 3-4, par. [0034] and [0035] and Fig. 2, element 132) and including memory (pgs. 3-4, par. [0035] and Fig. 1, element 106), the infusion pump being programmed to run a delivery program (pgs. 3-4, par. [0034] and [0035] and Fig. 2, element 132), the delivery program controlling the infusion pump to deliver the therapeutic agent according to a delivery schedule (pg. 3, par. [0032]-[0034], pg. 8, par. [0073] and Fig. 6, BOLUS DELIVERY), the method comprising:

storing a data set in the memory (pgs. 3-4, par. [0035] and Fig. 1, element 106), the data set including a set of operating parameters defining a delivery schedule (pg. 6, par. [0054]; i.e. corresponding operating parameters and cells, e.g. Max Bolus: 5.7U, Time Display: 24 Hr., Beep Volume: 3), at least one of the operating parameters being a uniquely identifying name (pg. 7, par. [0063] and Fig. 5; i.e. Susp. On at 12:57 AM); and

running the delivery program (pg. 8, par. [0073] and Fig. 6), the delivery program executing the set of operating parameters thereby controlling the infusion pump to deliver the therapeutic agent according to the delivery schedule defined by the set of operating parameters (pg. 6, par. [0057] and [0059]).

Estes teaches to a method substantially the same as claimed but does not expressly teach selecting one unique identifying name (pg. 7, par. [0063] and Fig. 5;

Page 9

i.e. Susp. On at 12:57 AM); and running the delivery program wherein the delivery program executes the operating parameters identified by the selected unique identifying name (pg. 6, par. [0057] and [0059]).

Gargano teaches to a field for the selection of an identifying a name (col. 11, lines 40-47; i.e. the "drug name"); and running the delivery program wherein the delivery program executes the operating parameters identified by the selected identifying name (col. 6, lines 19-30; i.e. selection the "drug name" initiates a delivery program).

Therefore, it would have been obvious to a person of ordinary skill in the art at the time of applicant's invention to modify the teaching of Estes to include a field for the selection of an identifying a name; and running the delivery program wherein the delivery program executes the operating parameters identified by the selected identifying name to provide a method of customization entry of drug information for a wide range of drug types and chemistries (col. 1, lines 28-34).

- 12. As per claim 19, Estes teaches an infusion pump (pgs. 2-3, par. [0027] and Fig. 1, element 100) comprising:
 - a pump mechanism (pg. 3, par. [0029]);

memory storing a data set (pgs. 3-4, par. [0035] and Fig. 1, element 106), the data set including a set of operating parameters defining a delivery schedule (pg. 6,

par. [0054]; i.e. corresponding operating parameters and cells, e.g. Max Bolus: 5.7U, Time Display: 24 Hr., Beep Volume: 3), at least one of the operating parameters being a uniquely identifying name (pg. 7, par. [0063] and Fig. 5; i.e. Susp. On at 12:57 AM); and

a processor (pg. 3, par. [0034]; e.g. PC, laptop) arranged to control the pump mechanism and in data communication with the memory (pgs. 3-4, par. [0034]), the processor being programmed to assign the set of operating parameters (pg. 6, par. [0054]; i.e. corresponding operating parameters and cells, e.g. Max Bolus: 5.7U, Time Display: 24 Hr., Beep Volume: 3) to the delivery program (pg. 8, par. [0073] and Fig. 6, BOLUS DELIVERY) and to execute the set of operating parameters thereby controlling the pump mechanism to deliver the therapeutic agent according to the delivery schedule (pg. 8, par. [0073] and Fig. 6, BOLUS DELIVERY).

Estes teaches to a method substantially the same as claimed but does not expressly teach the delivery program upon selection of the uniquely identifying name (pg. 7, par. [0063] and Fig. 5; i.e. Susp. On at 12:57 AM).

Gargano teaches the delivery program upon selection of the identifying name (col. 6, lines 19-30; i.e. selection the "drug name" initiates a delivery program).

Therefore, it would have been obvious to a person of ordinary skill in the art at the time of applicant's invention to modify the teaching of Estes to include the delivery program upon selection of the identifying name to provide a method of customization

entry of drug information for a wide range of drug types and chemistries (col. 1, lines 28-34).

- 13. Claims 2-7, 9-11, 13-18 and 20-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Estes in view of Gargano in further view of U.S. Patent Publication No. 2003/0011646 A1 (hereinafter Levine).
- 14. As per claim 2, Estes teaches the table includes a plurality of rows (pg. 6, par. [0054]; i.e. corresponding operating parameters and cells, e.g. Max Bolus: 5.7U, Time Display: 24 Hr., Beep Volume: 3).

Estes does not expressly teach each row relating to a different set of operating parameters, each set of operating parameters defining a different delivery schedule for the pump.

Gargano teaches to different fields relating to different operating parameters for the pump (col. 11, lines 40-49; e.g. syringe manufacturer and size; infusion units or type; mode or drug name; concentration; patient weight; infusion rate; bolus amount and duration; and dose amount, dose duration, number of doses and dose interval).

Gargano does not expressly teach each row relating to a different set of operating parameters, each set of operating parameters defining a different delivery schedule for the pump.

Art Unit: 2121

Levine teaches each row relating to a different set of parameters (pg. 2, par. [0038], pg. 11, par. [0147] and Fig. 23; i.e. dosage and frequency amount of a medication), each set of parameters defining a different delivery schedule (pg. 2, par. [0038], pg. 11, par. [0147] and Fig. 23; i.e. each row represents individual medications, and dosages and frequency amounts of each individual medication).

Therefore, it would have been obvious to a person of ordinary skill in the art at the time of applicant's invention to modify the teaching of Estes to include different fields relating to different operating parameters for the pump to provide a method of customization entry of drug information for a wide range of drug types and chemistries (Gargano: col. 1, lines 28-34); and each row relating to a different set of parameters, each set of parameters defining a different delivery schedule to increase patient compliance, by replicating the experience of the patient visiting an actual clinic (Levine: pg. 1, par. [0009]).

- 15. As per claim 3, Estes teaches as set forth above at least one cell within each row is **configured for (as opposed to actually having)** a unique identifying name, wherein the unique identifying name identifies the operating parameters in the same row of as the unique identifying name (pg. 7, par. [0063] and Fig. 5; i.e. Susp. On at 12:57 AM).
 - If, however the prior art is interpreted differently by a third party, the base

reference and secondary reference teach "at least one cell within each row is configured for (as opposed to actually having) a unique identifying name, wherein the unique identifying name identifies the operating parameters in the same row of as the unique identifying name" as follows:

Estes teaches to a method substantially the same as claimed but does not expressly teach one cell within each row is **configured for (as opposed to actually having)** a unique identifying name, wherein the unique identifying name identifies the operating parameters in the same row of as the unique identifying name (pg. 7, par. [0063] and Fig. 5; i.e. Susp. On at 12:57 AM).

Gargano teaches to a field **configured for identifying (as opposed to actually identifying)** a name (col. 11, lines 40-47; i.e. the "drug name"), wherein the identifying name identifies the parameters of the identifying name (col. 11, lines 40-47; e.g. concentration; infusion rate; bolus amount and duration; and dose amount, dose duration, number of doses and dose interval).

Gargano does not expressly teach one cell within each row is **configured for**(as opposed to actually having) a unique identifying name, wherein the unique identifying name identifies the parameters in the same row of as the unique identifying name.

Art Unit: 2121

Levine teaches one cell within each row is **configured for (as opposed to actually having)** a unique identifying name (Fig. 23, i.e. the name of "Medication" entered by the user), wherein the unique identifying name identifies the parameters (i.e. frequencies and dosages of the named "Medication(s)" entered by the user) in the same row of as the unique identifying name (pg. 2, par. [0038], pg. 11, par. [0147] and Fig. 23).

Therefore, it would have been obvious to a person of ordinary skill in the art at the time of applicant's invention to modify the teaching of Estes to include a field **configured for identifying (as opposed to actually identifying)** a name, wherein the identifying name identifies the parameters of the identifying name to provide a method of customization entry of drug information for a wide range of drug types and chemistries (Gargano: col. 1, lines 28-34); and one cell within each row is **configured for (as opposed to actually having)** a unique identifying name, wherein the unique identifying name identifies the parameters in the same row of as the unique identifying name to increase patient compliance, by replicating the experience of the patient visiting an actual clinic (Levine: pg. 1, par. [0009]).

16. As per claim 4, Estes teaches as set forth above the pump has memory (Fig. 2, element 106) and runs a delivery program and downloading the operating parameters includes downloading the operating parameters into the pump includes downloading

Art Unit: 2121

the operating parameters into the memory (pgs. 3-4, par. [0035]; i.e. downloading the operating parameters from Fig. 2, element 132).

- 17. As per claim 5, Estes teaches as set forth above the pump is programmed to run a delivery program, the method further comprising running the delivery program, thereby executing the operating parameters (pg. 8, par. [0073] and Fig. 6).
- 18. As per claim 6, Estes teaches as set forth above the pump has memory (Fig. 2, element 106) and is programmed to run a delivery program (pgs. 3-4, par. [0035]; i.e. downloading the operating parameters from Fig. 2, element 132), the method further comprising:

downloading all rows of operating parameters to the infusion pump (pgs. 3-4, par. [0035] and Figs. 3A, element 300); and storing the operating parameters in the memory (pgs. 3-4, par. [0035]).

- 19. As per claim 7, Estes teaches as set forth above selecting one unique identifying name (pg. 7, par. [0063] and Fig. 5; i.e. Susp. On at 12:57 AM); and running the delivery program wherein the delivery program executes the operating parameters identified by the selected unique identifying name (pg. 6, par. [0057] and [0059]).
- If, however the prior art is interpreted differently by a third party, the base reference and secondary reference teach "selecting one unique identifying and running

the delivery program wherein the delivery program executes the operating parameters identified by the selected unique identifying name" as follows:

Estes teaches to a method of substantially the same as claimed but does not expressly teach above selecting one identifying name (pg. 7, par. [0063] and Fig. 5; i.e. Susp. On at 12:57 AM); and running the delivery program wherein the delivery program executes the operating parameters identified by the selected unique identifying name (pg. 6, par. [0057] and [0059]).

Gargano teaches to a field for identifying a name (col. 11, lines 40-47; i.e. the "drug name") and running the delivery program wherein the delivery program executes the operating parameters identified by the selected unique identifying name (col. 6, lines 19-30; i.e. selection the "drug name" initiates a delivery program).

Therefore, it would have been obvious to a person of ordinary skill in the art at the time of applicant's invention to modify the teaching of Estes to include a field for identifying a name to provide a method of customization entry of drug information for a wide range of drug types and chemistries (col. 1, lines 28-34).

20. As per claim 9, Estes teaches an apparatus (Fig. 2, element 132) for programming an infusion pump (pgs. 2-3, par. [0027]), pgs. 3-4, par. [0034] and [0035] and Fig. 1, element 100), the pump programmed to execute a delivery program (pgs. 3-4, par. [0034]), the delivery program programmed to process operating

Application/Control Number: 10/087,449

Art Unit: 2121

parameters (pg. 3, par. [0032] and [0033]), the operating parameters defining operating of the pump (pg. 6, par. [0054]; i.e. corresponding operating parameters and cells, e.g. Max Bolus: 5.7U, Time Display: 24 Hr., Beep Volume: 3), the apparatus comprising:

a data port (pg. 3, par. [0034] and Fig. 2, e.g. PC, laptop);

a data entry device (pg. 3, par. [0034] and Fig. 2, e.g. PC, laptop); and

a processor in data communication with the data port and the data entry device (pg. 3, par. [0034]; e.g. PC, laptop),

generating a table (Fig. 3A, element 300), the table containing a row, the row having a plurality of cells (pg. 6, par. [0054]; i.e. corresponding operating parameters and cells, e.g. Max Bolus: 5.7U, Time Display: 24 Hr., Beep Volume: 3), each cell in the row relating to a different operating parameter for the delivery program (pg. 6, par. [0054]; i.e. corresponding operating parameters and cells, e.g. Max Bolus: 5.7U, Time Display: 24 Hr., Beep Volume: 3);

- (b) receive data from the data entry device and display the data in one or more of the cells (pgs. 3-4, par. [0035], Fig. 1 and 2, elements 106 and 132 and Fig. 3A, element 300); and
- (c) download the operating parameters displayed (col. 6, par. [0054]) in the cells to the infusion pump (pgs. 3-4, par. [0035], Fig. 1 and 2, elements 106 and 132 and Fig. 3A, element 300).

Estes does not expressly teach the processor programmed to generate a table.

Gargano does not expressly teach the processor programmed to generate a table.

Levine teaches the processor programmed to (a) generate a table (pg. 2, par. [0038], pgs. 4-5, par. [0090], pg. 11, par. [0147] and Fig. 23, element 1800).

Therefore, it would have been obvious to a person of ordinary skill in the art at the time of applicant's invention to modify the teaching of Estes in view of Gargano to include the processor programmed to (a) generate a table to increase patient compliance, by replicating the experience of the patient visiting an actual clinic (pg. 1, par. [0009]).

21. As per claim 10, Estes teaches the processor is further programmed to generate a plurality of rows in the table rows (pg. 6, par. [0054]; i.e. corresponding operating parameters and cells, e.g. Max Bolus: 5.7U, Time Display: 24 Hr., Beep Volume: 3).

Estes does not expressly teach each row relating to a different set of operating parameters, each set of operating parameters defining a different delivery schedule for the pump.

Gargano teaches to a different set of different set of operation parameters (col. 11, lines 40-49; i.e. entering new information (e.g. syringe manufacturer and size; infusion units or type; mode or drug name; concentration; patient weight; infusion rate;

bolus amount and duration; and dose amount, dose duration, number of doses and dose interval) of a new drug by user selection), each set of operating parameters defining a different delivery schedule for the pump (14, lines 33-36; i.e. the delivery schedule for a specific "drug name").

Gargano does not expressly teach each row relating to a different set of operating parameters.

Levine teaches to each row relating to a different set of parameters (pg. 2, par. [0038], pg. 11, par. [0147] and Fig. 23; i.e. frequencies and dosages of the named "Medication(s)" entered by the user).

Therefore, it would have been obvious to a person of ordinary skill in the art at the time of applicant's invention to modify the teaching of Estes to include a different set of different set of operation parameters, each set of operating parameters defining a different delivery schedule for the pump to provide a method of customization entry of drug information for a wide range of drug types and chemistries (Gargano: col. 1, lines 28-34); and each row relating to a different set of parameters to increase patient compliance, by replicating the experience of the patient visiting an actual clinic (Levine: pg. 1, par. [0009]).

22. As per claim 11, Estes teaches as set forth above each row in the table includes at least one cell **configured to receive (as opposed to actually receiving)** a

unique identifying name, wherein the unique identifying name identifies the operating parameters in the same row as the unique identifying name (pg. 7, par. [0063] and Fig. 5; i.e. Susp. On at 12:57 AM).

If, however the prior art is interpreted differently by a third party, the base reference and secondary reference teach "each row in the table includes at least one cell **configured to receive (as opposed to actually receiving)** a unique identifying name, wherein the unique identifying name identifies the operating parameters in the same row as the unique identifying name" as follows:

Estes teaches to a method substantially the same as claimed but does not expressly teach each row in the table includes at least one cell **configured to receive** (as opposed to actually receiving) a unique identifying name, wherein the unique identifying name identifies the operating parameters in the same row as the unique identifying name (pg. 7, par. [0063] and Fig. 5; i.e. Susp. On at 12:57 AM).

Gargano teaches to a field for identifying a name (col. 11, lines 40-47; i.e. the "drug name"), wherein the identifying name identifies the operating parameters of the identifying name (col. 11, lines 40-47; e.g. concentration; infusion rate; bolus amount and duration; and dose amount, dose duration, number of doses and dose interval).

Gargano does not expressly teach each row in the table includes at least one cell configured to receive (as opposed to actually receiving) a unique identifying name,

Art Unit: 2121

wherein the unique identifying name identifies the operating parameters in the same row as the unique identifying name.

Levine teaches each row in the table includes at least one cell **configured to**receive (as opposed to actually receiving) a unique identifying name (Fig. 23, i.e. name of "Medication"), wherein the unique identifying name identifies the parameters in the same row as the unique identifying name (pg. 2, par. [0038], pg. 11, par. [0147] and Fig. 23; i.e. frequencies and dosages of the named "Medication(s)" entered by the user).

Therefore, it would have been obvious to a person of ordinary skill in the art at the time of applicant's invention to modify the teaching of Estes to include a field for identifying a name, wherein the identifying name identifies the operating parameters of the identifying name to provide a method of customization entry of drug information for a wide range of drug types and chemistries (Gargano: col. 1, lines 28-34); and each row in the table includes at least one cell configured to receive a unique identifying name, wherein the unique identifying name identifies the parameters in the same row as the unique identifying name to increase patient compliance, by replicating the experience of the patient visiting an actual clinic (Levine: pg. 1, par. [0009]).

Art Unit: 2121

23. As per claim 13, Estes teaches as set forth above downloading the data set to the pump from a computer (pgs. 3-4, par. [0035], Fig. 1 and 2, elements 106 and 132 and Fig. 3A, element 300).

- 24. As per claim 14, Estes teaches as set forth above storing a data set in the memory (pgs. 3-4, par. [0035] and Fig. 1, element 106), includes storing two or more data sets in the memory (pgs. 3-4, par. [0035] and Fig. 1, element 106), each data set including a set of operating parameters defining a delivery schedule (Fig. 3A, element 300; Fig. 2, elements 100 and 132; pgs. 3-4, par. [0035]; Fig. 5, Alarm/Event Marker Table; pg. 6, par. [0060], i.e., "The graph is derived from carbohydrate consumption events from the event marker table that have been logged by the user"; pg. 7, [0063], i.e., "the time change is displayed in either 12 or 24 hr format depending on user's settings"; pg. 7, par. [0064], i.e., "At least some of these events can be taken as inputs to the bolus estimator 128 in calculating an insulin dosage").
- 25. As per claim 15, Estes teaches as set forth above to generating a menu, the menu including at least one menu item corresponding to one of the unique identifying names; and wherein selecting the unique identifying name includes selecting the menu item (pg. 8, par. [0073] and Fig. 6, element "Main Menu").

Art Unit: 2121

- 26. As per claim 16, Estes teaches wherein storing a data set in the memory (pgs. 3-4, par. [0035] and Fig. 1, element 106), includes storing two or more data sets in the memory (pgs. 3-4, par. [0035] and Fig. 1, element 106) includes storing a plurality of data sets in memory, each data set including a set of operating parameters defining a separate delivery schedule (Fig. 3A, element 300; Fig. 2, elements 100 and 132; pgs. 3-4, par. [0035]; Fig. 5, Alarm/Event Marker Table; pg. 6, par. [0060], i.e., "The graph is derived from carbohydrate consumption events from the event marker table that have been logged by the user"; pg. 7, [0063], i.e., "the time change is displayed in either 12 or 24 hr format depending on user's settings"; pg. 7, par. [0064], i.e., "At least some of these events can be taken as inputs to the bolus estimator 128 in calculating an insulin dosage").
- 27. As per claim 17, Estes teaches as set forth above to generating a menu includes generating a menu having at least one menu item corresponding to a unique identifying name from one data set and at least one menu item corresponding to a unique identifying name from another data set (pg. 8, par. [0073] and Fig. 6, element "Main Menu").
- 28. As per claim 18, Estes teaches as set forth above to the execution of the delivery program from the set of operating parameters in one data set to the set of operating parameters in another data set (pq. 8, par. [0074]).

Art Unit: 2121

29. As per claim 20, Estes teaches set forth above a data port (pg. 3, par. [0034] and Fig. 2, e.g. PC, laptop), the processor being further arranged to control downloading of the data set and storage of the data set into the memory (pgs. 3-4, par. [0035], Fig. 1 and 2, elements 106 and 132 and Fig. 3A, element 300).

- 30. As per claim 21, Estes teaches as set forth above the memory stores two or more data sets in the memory (pgs. 3-4, par. [0035] and Fig. 1, element 106), each data set including a set of operating parameters defining a delivery schedule (Fig. 3A, element 300; Fig. 2, elements 100,132; 0035, lines 1-7; Fig. 5, Alarm/Event Marker Table; Page 6, [0060], lines 1-6, i.e., "The graph is derived from carbohydrate consumption events from the event marker table that have been logged by the user"; Page 7, [0063], lines 1-13, i.e., "the time change is displayed in either 12 or 24 hr format depending on user's settings"; [0064], lines 13-15, i.e., "At least some of these events can be taken as inputs to the bolus estimator 128 in calculating an insulin dosage").
- 31. As per claim 22, Estes teaches as set forth above the processor is further programmed to generate a menu, the menu including at least one menu item corresponding to one of the unique identifying names, wherein selecting the menu item is at least one step in beginning execution of the delivery program (pg. 8, par. [0073] and Fig. 6, element "Main Menu").

Application/Control Number: 10/087,449

Page 25

Art Unit: 2121

32. As per claim 23, Estes teaches as set forth above the memory stores two or more data sets (pgs. 3-4, par. [0035] and Fig. 1, element 106), each data set including a set of operating parameters defining a separate delivery schedule (Fig. 3A, element 300; Fig. 2, elements 100 and 132; pgs. 3-4, par. [0035]; Fig. 5, Alarm/Event Marker Table; pg. 6, par. [0060], i.e., "The graph is derived from carbohydrate consumption events from the event marker table that have been logged by the user"; pg. 7, [0063], i.e., "the time change is displayed in either 12 or 24 hr format depending on user's settings"; pg. 7, par. [0064], i.e., "At least some of these events can be taken as inputs to the bolus estimator 128 in calculating an insulin dosage").

- 33. As per claim 24, Estes teaches as set forth above the processor is further programmed to generate a menu, the menu including at least one menu item corresponding to a unique identifying name from one data set and at least one unique identifying name from another data set (pg. 8, par. [0073] and Fig. 6, element "Main Menu").
- 34. As per claim 25, Estes teaches as set forth above the processor is further programmed to switch execution of the delivery program from the set of operating parameters in one data set to the set of operating parameters in another data set (pg. 8, par. [0074]).

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

The following references are cited to further show the state of the art with respect to medical management systems.

U.S. Patent Publication No.2009/0177180 A1 discloses a method of adding additional VTBI to an ongoing infusion without stopping the infusion and with maintaining the infusion parameters.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer L. Norton whose telephone number is (571)272-3694. The examiner can normally be reached on Monday-Friday between 9:00 a.m. - 5:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Albert Decady can be reached on 571-272-3819. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you

Art Unit: 2121

have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Albert DeCady/ Supervisory Patent Examiner Art Unit 2121

/JLN/